

FEB 14 2001

Attachment 4 510(k) Summary

| Category: | Comments |
|---|--|
| Sponsor: | Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134 |
| Correspondent: | Andrea L. Boumis Associate II, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134 |
| Contact Numbers: | Phone: 408.895.3625 Fax: 408.895.2202 |
| Device Common Name | Electrode Recording and Pacing Catheter |
| Device Proprietary Name | Constellation® Multiple Electrode Recording and Pacing Catheter |
| Device Classification | Class II, MTD |
| Predicate Device | Electrode Recording and Pacing Catheter |
| Predicate Device Manufacturer(s) | Boston Scientific/EP Technologies Inc. |
| Predicate Device Proprietary Name(s) | Constellation® Multiple Electrode Recording and Pacing Catheter |
| Predicate Device Classification Number | MTD |
| Predicate Device Classification(s) | 21 CFR § 870.1220 |

Date Summary Was Prepared:

December 6, 2000

Description of the Device:

The Boston Scientific/EP Technologies (EPT) Constellation® Multiple Electrode Recording and Pacing Catheter is a sterile, single use device used to detect and record electrical potentials from the endocardial surfaces of the heart, and to deliver externally generated pacing stimuli. The distal, expandable "basket" assembly is, in essence, eight miniature octapolar "catheters". The basket assembly contains an array of between 32 to 64 electrodes mounted along eight resilient support structures called "splines". Several configurations are available, including unipolar (electrodes evenly spaced), bipolar (electrodes evenly distributed into pairs), and lower density arrays. EPT furnishes the Constellation® Catheter either with or without the Duraflo® coating. EPT also

furnishes accessories that include EPT Constellation Accessory Cables (sterile, re-useable), an EPT Constellation Pacing Switchbox (non-sterile, re-useable), and EPT Constellation extension cables (non-sterile, re-useable).

Intended Use:

For use in right atrial electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Constellation® Multiple Electrode Recording and Pacing Catheter System may also be used for delivery of externally generated pacing stimuli.

**Technological
Characteristics:**

The basket assembly contains between 32 and 64 electrodes in unipolar, bipolar or low-density arrays, mounted along eight resilient support structures called "splines". The Constellation® Catheter is delivered to the right atrium using a Guiding Catheter. After proper position has been achieved, the Guiding Catheter is withdrawn allowing the basket assembly to expand and achieve intimate contact with the endocardium. The physician either connects the electrical connector of the catheter to an accessory pacing switchbox, or selects the output of cardiac electrograms according to the electrode, or electrode pair, of interest. Alternatively, the catheter may be connected to a commercially available EGM recorder or an external pulse wave generator. No new technology or circuitry is with the transmission of electrical signals to or from the endocardium – the Constellation® Catheter relies on platinum-iridium alloy, ring electrodes (1.25mm in length) whose circuitry is identical to standard electrode and pacing catheters. Additionally, the electrical connections made are similar to those for commercially available electrode recording and pacing catheters.

**Comparison to
Predicate
Device:**

| Predicate Device | Constellation® Catheter 38, 48, 60 & 75 mm | 31 mm Constellation® Catheter |
|-------------------------|---|--|
| 510(k) Reference | K983171; K992777; K000277 | Current Submission |
| Intended Use | Intracardiac electrophysiological mapping and or pacing | Same |
| Device Description | Multiple Electrode Mapping and Pacing Catheter | Same |
| Single Use? | Yes | Same |
| EO Sterilized? | Yes | Same |
| Manufacturer | BSC/EPT | Same |
| Device Classification | Class II / MTD 21 CFR 870.1220 | Same |

**Summary of the
Non-clinical
Data:**

Where appropriate, testing conformed to the requirements of 21 CFR Part 58 (Good Laboratory Practices (GLP)). Specifically, non-clinical tests conducted for the EPT Mapping and Ablation System, included biocompatibility, sterility, in vivo performance, reliability, physical integrity, and electrical integrity testing.

**Abstract of the
Clinical Data:**

As part of IDE G940162, used to support approved 510(k) K983171, the Constellation catheter was used in the right atrium in 116 patients. Twenty-five atrial patients received standard catheters. The complication rates for the atrial patients were 16% (17/116) for the Constellation Group and 14% (3/25) for the standard group.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2001

Ms. Andrea L. Ruth
Boston Scientific Corp.
EP Technologies, Inc.
2710 Orchard Parkway
San Jose, CA 95134

Re: K003782
Constellation Catheter, Model 8031 – 31mm
Regulatory Class: II (two)
Product Code: MTD
Dated: January 12, 2001
Received: January 16, 2001

Dear Ms. Ruth:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

WARNING: The use of this device in conjunction with radiofrequency ablation, as part of the diagnosis and treatment of cardiac arrhythmias, may pose an increased risk of adverse events, such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion.

The Warning must be presented within a black box, and the font size of the text should be at least 2 points larger than any surrounding text. The Warning must be present on the first page of your Operator's Manual, and on the packaging for each individual device.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

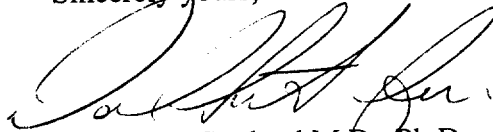
Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers

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Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bernard E. Statland". The signature is fluid and cursive, with a large initial "B" and "S".

Bernard E. Statland M.D., Ph.D.

Director

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Attachment 2
Intended Use Statement**

510(k) Number (if known): K003782

Device Name: Constellation® Multiple Electrode Recording and Pacing Catheter
(31 mm)

Indication for Use:

For use in right atrial electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Constellation® Multiple Electrode Recording and Pacing Catheter System may also be used for delivery of externally generated pacing stimuli.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for W. E. Schaus

Prescription Use ☒

OR

Over-The-Counter Use ☐

(Per 21 CFR 801.109)

(Optional Format 1-2-96)